Konformitätserklärung
Declaration of Conformity

Wir | We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung, dass das Produkte

Original Perfusor® Syringe 50 ml
3-teilige Einwegspritzen mit Lock Konnektor zur Verwendung mit geeigneten Pumpen für die Regionalanästhesie, Typ NRFit®
Basis UDI-DI: 40392390000007802S
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmt

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)

hereby declare in our own responsibility that the product

Original Perfusor® Syringe 50 ml
3-piece Single-use syringe with Lock connector for usage with compatible pumps for Regional Anaesthesia, Type NRFit®
Basic UDI-DI: 40392390000007802S
(article numbers see attachment I)

is in conformity with the requirements of the Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Classification
according to annex VIII of the Regulation named above
Class IIa

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Valid until
according to our valid EU Certificate
(No. G10 012974 0611)

Effective

Anlage I / Attachment I

Basic UDI-DI: 403923900000007802S

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8728845F-01	Original Perfusor® Syringe 50 ml	IIa

Effective

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR

Title: Declaration of Conformity - 160-004-MDR - OPS NRFit Initiator: Julia2 ? Mueller

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Mueller, Julia2 (hampjude)
Title: Senior Manager Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 23 May 2024, 08:49 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 23 May 2024, 10:10 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 23 May 2024, 10:51 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective